

Application No. 10/622,207  
Reply to Office Action dated February 11, 2008  
Amendment dated May 20, 2008

**REMARKS**

This amendment is submitted in response to the Office Action mailed February 11, 2008. Claims 60-67 and 69 remain pending in the application prior to this amendment, and stand rejected. Claims 60 and 69 have been amended herein. Applicants respectfully request reconsideration in view of the amendments and following remarks.

**Claims Rejected under 35 U.S.C. §112**

Claim 69 stands rejected under 35 U.S.C. §112, second paragraph, with respect to the recitation of "T-bar" in the claim. Claim 69 has been amended to recite the structure associated with the T-bars discussed in the application, for example, at page 14, line 29-page 15, line 17; and with reference to FIGS. 10 and 13C. Applicants assert that no new matter has been added by the amendment to claim 69. Accordingly, Applicants respectfully request that the rejection of claim 69 under 35 U.S.C. §112 be withdrawn.

**Claims Rejected under 35 U.S.C. §102**

Claims 60-67 and 69 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0167539 to Kuehn et al. Claim 60 is the only independent claim of this rejected group, and has been amended herein to recite "three or more non-plicating fasteners configured to be individually fixed to tissue adjacent the annulus of the heart valve at spaced locations by piercing the

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tissue without plicating the tissue at the spaced locations," and "an elongate tensioning element coupled with the non-plicating fasteners and configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together." Applicants assert that amended claim 60 is not disclosed by Kuehn '539. Kuehn '539 is directed to a device for repairing mitral and tricuspid valves wherein a pair of barbed needles 222 may be coupled at their ends to sutures 226. At paragraph 0090, Kuehn '539 states that the suture 226 may be connected to the ends of the needles 222 and looped around the other needle so that the needles may be drawn together by pulling on the ends of the sutures. Kuehn '539 does not disclose three or more non-plicating fasteners coupled together by an elongate tensioning element configured to be tensioned by pulling on only one end of the tensioning element. Even if the structure of Kuehn '539 were modified to include three needles 222, a single tensioning element could not be coupled to the three barbed needles 222 in a manner that would place the barbed needles 222 closer together by pulling on only one end of the suture, as set forth in claim 60.

Claims 61-67 and 69 each depend from independent claim 60 and are in condition for allowance for at least the reasons discussed above with respect to claim 60. Accordingly, Applicants respectfully request that the rejections of claims 61-67 and 69 over Kuehn '539 be withdrawn.

Claims 60-62, 65, and 67 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2001/0018611 to Solem et al. Claim 60 is the only independent claim of this rejected group, and has been amended

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as discussed above. FIGS. 12-17 of Solem '611, cited by the Examiner, is directed to an apparatus for reducing a mitral valve annulus using stent sections 23, 24, 25, 30, 31 positioned in the coronary sinus. The stent sections are secured within the coronary sinus by expanding to engage the walls of the coronary sinus. Accordingly, the stent sections of Solem '611 are not configured to be fixed to tissue adjacent the annulus of the heart valve by piercing the tissue, as set forth in claim 60. For at least these reasons, Applicants respectfully request that the rejection of claim 60 over Solem '611 be withdrawn.

Claims 61, 62, 65, and 67 each depend from independent claim 60 and are in condition for allowance for at least the reasons discussed above with respect to independent claim 60. Accordingly, Applicants respectfully request that the rejections of claims 61, 62, 65, and 67 over Solem '611 be withdrawn.

### **Claims Rejected under 35 U.S.C. §103**

Claims 63, 64, and 69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Solem '611 in view of Kuehn '539. Claims 63, 64, and 69 each depend from independent claim 60 and are, therefore, in condition for allowance for at least the reasons discussed above with respect to independent claim 60. Specifically, Solem '611 discloses various structure for treating mitral annulus dilation. In one embodiment, shown and described with reference to FIGS. 12-17, Solem '611 discloses apparatus wherein individual stent sections 23, 24, 25, 30, 31 are positioned within a coronary sinus and are expanded to engage the interior walls of the coronary sinus,

thereby securing the stent sections to the coronary sinus. (See e.g., Solem '611 at paragraph 0025.) The stent sections are connected by wires 26, 27, 35, 36 for reducing the distance between the respective stent sections. In this embodiment, Solem '611 does not disclose non-plicating fasteners configured to be fixed to tissue adjacent the annulus of a heart by piercing the tissue, as discussed above.

Because the embodiments of FIGS. 12-17 are secured within the coronary sinus by expansion of the stent sections, further anchoring using T-bars, as suggested by the Examiner, is not required. Moreover, claim 69 has been amended herein to recite that the non-plicating fasteners comprise elongate members coupled to the tensioning element at a location intermediate the terminal ends. Kuehn '539 does not disclose such structure, nor is it apparent how the stent sections of Solem '611 could be modified to include such structure.

In a different embodiment, depicted in FIGS. 2-7 referred to by the Examiner, the device includes an elongate body 8 having anchors 10 for engaging the walls of the coronary sinus. The elongate body 8 is convertible from a first, straightened shape (as depicted in FIG. 2) to a second, arcuate shape (depicted in FIG. 3) when a cover sheath 11 and stabilizing instrument 12 are removed from the elongate body 8. This embodiment relies upon shape memory characteristics of the elongate body to convert to the arcuate shape, and does not utilize tensioning elements, such as the wires used in the embodiments of FIGS. 12-17. Accordingly, the embodiments of FIGS. 2-7 of Solem '611 do not disclose or even require the use of a tensioning element, as set forth in claim 60, and Kuehn '539 fails to disclose a modification of Solem '611 that cures this

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deficiency. For at least the reasons discussed above, Applicants respectfully request that the rejections of claims 63, 64, and 69 over Solem '611 in view of Kuehn '539 be withdrawn.

Claim 66 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Solem '611. Claim 66 depends from independent claim 60 and is, therefore, in condition for allowance for at least the reasons discussed above with respect to independent claim 60. Specifically, Solem '611 fails to disclose the combination of features recited in claim 60, including "three or more non-plicating fasteners configured to be fixed to tissue adjacent the annulus of the heart valve by piercing the tissue," and "an elongate tensioning element coupled with the non-plicating fasteners," as discussed above. For at least these reasons, Applicants respectfully request that the rejection of claim 66 over Solem '611 be withdrawn.

### **Conclusion**

In view of the remarks and the foregoing amendments to the claims, Applicants believe this application is in condition for allowance and respectfully request allowance of the pending claims. If the Examiner believes any issue requires further discussion, the Examiner is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. The Examiner's prompt attention to this matter is appreciated.

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Applicants do not believe that any fee is due in connection with this submission other than the fee of \$60 for a one month extension of time. However, if any fees are necessary to complete this communication, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account No. 23-3000.

Respectfully submitted,

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